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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,234	04/07/2004	Ivan Labat	821A	9734

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NUVELO, INC
201 INDUSTRIAL ROAD
SUITE 310
SAN CARLOS, CA 94070

EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,234	LABAT ET AL.	
	Examiner	Art Unit	
	Jeanine A. Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-9, drawn to a method for identifying a patient with a higher preeclampsia by detecting nucleic acid sequence, classified in class 435, subclass 6.

II. Claims 2-8, 10, drawn to a method for identifying a patient with a higher preeclampsia by detecting polypeptide, classified in class 435, subclass 7.1.

III. Claims 11, 13-14 drawn to an antibody, classified in class 424, subclass 130.1.

IV. Claims 12, drawn to a polynucleotide, classified in class 536, subclass 23.1.

V. Claim 15, drawn to a polypeptide, classified in class 530, subclass 350.

VI. Claim 16, drawn to a method of treating preeclampsia by treating with an antibody, classified in class 424, subclass 130.1.

VII. Claim 17, drawn to a method of treating preeclampsia by treating with an polypeptide, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

A) Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the nucleic acids may be use in materially different methods. The nucleic acids may be used for isolation, purification, antisense methods and aptamer screening methods, for example.

B) Inventions (II and VII) and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide may be used in materially different methods aside from the method of treating or the method of detecting increased risk for preeclampsia. The polypeptides may be used for raising antibodies, for example.

C) Inventions (III) and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide may be used in materially different methods aside from the method of treating preeclampsia. The antibodies may be used for detecting proteins, for example.

D) The inventions of Groups III, IV and V are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group IV is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group V is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets,

and hydrophobic loops (transmembrane domain). The antibody of Group III is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Groups III, IV and V can be used in materially different processes, for example, the DNA of Group IV can be used in hybridization assays, the antibody of Group III can be used in immunoassay, the polypeptide of Group V can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different.

Furthermore, searching the inventions of groups III, IV, V together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups IV and V have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive.

A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of

novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group III. Furthermore, antibodies which bind to an epitope of a polypeptide of group II may be known even if a polypeptide of group V is novel. The technical literature search for the polypeptide of group V and the antibody of group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

Therefore, the inventions of Groups III, IV and V are patentably distinct from each other.

E) The inventions of Group I, II, VI, and VII are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group I is for detecting preeclampsia using nucleic acids; Group II for detecting preeclampsia using polypeptides. Group VI is for treating using a nucleic acid. Alternatively, the method of Group VII is for treating using polypeptides. Furthermore, the distinct steps and products require separate and distinct searches. Therefore the methods are distinct over one another.

F) Group IV and (II, VI, VII) are patentable distinct inventions because the nucleic acid of Group IV is not relied upon in the method of Group II, VI or VII. Instead Group II and VII uses polypeptides; Group VI uses an antibody. Therefore, the inventions are novel and unobvious over one another.

G) Group III and (I, II, VI, VII) are patentable distinct inventions because the antibody of Group II is not relied upon in the method of Group I, II, VI, VII. Instead Group II and VII uses polypeptides; Group I uses a nucleic acid. Therefore, the inventions are novel and unobvious over one another.

H) Group V and (I, VI) are patentable distinct inventions because the polypeptide of Group V is not relied upon in the method of Group I or VI. Instead Group I uses polynucleotides; Group VI uses an antibody. Therefore, the inventions are novel and unobvious over one another.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper. Further a search of each of these inventions would not be coextensive of a search for each of the other inventions.

Restriction Requirement Applicable to All Groups Requiring more than one Patentably Distinct Sequence:

SEQUENCE RESTRICTION REQUIREMENT

The claims require more than 850 polynucleotides or polypeptides and antibodies. Additionally, each group named above is subject to further restriction. Each group detailed above reads on patentably distinct sequence of nucleic and amino acid sequence. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each group.

Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect

on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications.

For the claims drawn to a combination of genes, namely one or more genes. A restriction is applied to each Group. As provided in MPEP 803.04, "Applicants will be required to select one combination for examination." The selected combination will be searched and examined. A combination may be as few as a single gene or as many genes as the combination of all the recited genes. Applicant is required to specifically indicate the single combination desired. All combinations containing the allowable sequences and any patentably indistinct sequences will be rejoined and allowed. Rejoinder will be permitted for claims requiring any allowable sequence(s). Any claims which have been restricted and nonselected and which are limited to the allowable sequence(s) will be rejoined and examined.

For an elected group drawn to an nucleic acid sequence, the applicant must further elect a nucleic acid sequence or a SPECIFIC combination of nucleic acid sequence. or an elected group drawn to an amino acid sequence, the applicant must further elect a amino acid .

Applicant is further required to distinctly point out the location in the drawings, figures, or SEQ IDS of the instant application to which the elected sequence is drawn. Please include in the selection of a sequence or specific combination of sequence the SEQ ID(s), the Genebank numbers) (or any other identifier), the table or figure number, and the row or column location in the table.

This is NOT an election of species. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35

U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that '[I]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). lt is noted that searching more than one of the claimed patentably distinct sequences represents a serious burden for the office.

Should applicant traverse on the ground that the nucleic acids and/or combinations of nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Notice for Rejoinder

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of**

the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272- 0745.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

J. Goldberg

Jeanine Goldberg
Primary Examiner
March 1, 2006